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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,383	10/27/2003	Ekambar R. Kandimalla	HYB-005US4	5766

7590 06/26/2007  
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EXAMINER

HORNING, MICHELLE S

ART UNIT	PAPER NUMBER
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1648

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06/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/694,383	<b>Applicant(s)</b> KANDIMALLA ET AL.	
	<b>Examiner</b> Michelle Horning	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-19 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is responsive to communication filed 5/10/2007. The status of the claims is as follows: claims 1-11 and 20-38 are canceled and claims 12 and 14 are under current examination while claims 13 and 15-19 are drawn to non-elected species. Applicant has elected the sequence set forth in SEQ ID NO:2. This sequence consists of 18 nucleic acids without any immunostimulatory moieties and read upon claims 12 and 14 (in part). No additional species were searched because the claims are not free of the art.

Applicant's election of SEQ ID NO:2 in the reply filed on 5/10/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Further, Applicant has stated the following in the reply filed on 5/10/2007: "Applicants do not understand the Examiner's position with regards to the structure/function relationship". To provide further clarification in response to the above statement, this relationship is briefly explained here. The structure of a molecule determines the molecule's function and in this instance, the molecule is the immunostimulatory oligonucleotide determined by its structural sequence. Differential sequences lead to differential functions.

#### ***Claim Rejections***

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20 and 22 of copending Application No. 10/694, 586.** Although the conflicting claims are not identical, they are not patentably distinct from each other because, while the claims differ in scope, both sets of claims are drawn to an immunostimulatory oligonucleotide containing a non-natural pyrimidine nucleoside.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/865, 245.** Although the conflicting claims are not identical, they are not patentably distinct from each other because, while the claims

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differ in scope, both sets of claims are drawn to an immunostimulatory oligonucleotide containing a non-natural pyrimide nucleoside.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 39 of copending Application No. 11/270, 805.** Although the conflicting claims are not identical, they are not patentably distinct from each other because, while the claims differ in scope, both sets of claims are drawn to an immunostimulatory oligonucleotide containing a non-natural pyrimide nucleoside.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/153, 054.** Although the conflicting claims are not identical, they are not patentably distinct from each other because, while the claims differ in scope, both sets of claims are drawn to an immunostimulatory oligonucleotide containing a non-natural pyrimide nucleoside.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-11 of copending Application No. 10/694, 418.** Although the conflicting claims are not identical, they are not patentably distinct from each other because, while the claims differ in scope, both sets of claims are drawn to an immunostimulatory oligonucleotide containing a non-natural pyrimide nucleoside.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 39-43 of copending Application No. 09/965, 116.** Although the conflicting claims are not identical, they are not patentably distinct from each other because, while the claims differ in scope, both sets of claims are drawn to an immunostimulatory oligonucleotide containing a non-natural pyrimide nucleoside.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. *It is noted, however, that the claims of application No. 09/965, 116 have been allowed, although a patent number has yet to be established.*

### **35 U.S.C. 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Application No. 10/365, 678 (1998, hereinafter as "Schwartz").** The limitations of the rejected claims above are as follows: 1. An immunostimulatory oligonucleotide comprising the sequence 5'-Um...U1-X1-X2-Y-Z-X3-X4-D1...Dm-3', wherein Y is a non-natural pyrimidine; Z is a guanosine; each X is a naturally occurring nucleoside; wherein both the U and D domains are upstream and downstream potentiation domains; and wherein m can be a number from 0 to 30; and 2. wherein the X's, U's and D's are naturally occurring nucleosides.

Schwartz teaches the limitations above. This reference discloses sequences in which at least one base has been substituted with a modified base and administration of said sequence modulates an immune response (see Technical Field). Paragraphs 59 and 60 further describes specific modified bases, including modified cytosines, which may be used in immunomodulatory oligonucleotides. Table 1 provides oligonucleotide sequences that meet the structural limitations of the claimed invention found in the formula of claim 1 (see page 13, SEQ ID NO: 2). More specifically, the modified base used within these sequences is a 5-bromocytosine, which is adjacent to a naturally occurring guanosine while the other bases are naturally occurring. Further, the SEQ ID NO: 2 has a total of 22 nucleotides, meeting the length requirement. Lastly, paragraph

11 describes the sequences flanking the CpG as influencing the immunostimulatory activity of an oligonucleotide which meets the limitation of a potentiation domain as defined by the instant specification.


**Conclusion**


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Michelle Horning  
Patent Examiner

  
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